

REMARKS

I. Real Party in Interest

The real party in interest is George H. Small, M.D., M.P.H. of 1415 Cindee Lane, Colton, CA 92324.

II. Related Appeals and Interferences

None.

III. Status of Claims

Claims 1-11 and 26-28 stand allowed. Claims 17-25 and 29, as amended, are pending for the Examiner's consideration. Claim 30 has been canceled without prejudice to Applicant's rights to file one or more continuing applications directed to that or other unclaimed subject matter.

IV. Status of Amendments

Based on the Examiner's agreement at the interview of February 2, 2005, Applicants expect that the Examiner will enter this Amendment and the accompanying Declaration Under 37 C.F.R. § 1.132, because the Amendment has amended claim 17 and claim 26 has been amended to depend from claim 1 as discussed at the interview and further detailed below. Each amendment is believed to reduce the issues for appeal.

V. Summary of Claimed Subject Matter

The allowed subject matter of claims 1-11 relates to an umbilical cord clamp that includes: a pair of arms each having a length in a generally V-shaped configuration having rear end portions associated at an apex and having free forward end portions normally disposed in spaced-apart relation and being movable towards each other for clamping an umbilical cord between the arms, a flared portion at the end of each arm, a grasping portion that is disposed on each arm transversely to the length thereof, which is distinct from the flared portion on that arm and which is sufficiently sized and shaped to extend a greater transverse distance than the flared portion to receive a finger or tool so as to facilitate grasping and closing of the clamp, and a locking portion for securing the arms together when the clamp is closed.

The subject matter that is presently rejected includes claims 17-25, which relates to an umbilical cord clamp that includes a pair of arms each having a length in a generally V-shaped configuration having rear end portions joined together at the apex thereof and having free

forward end portions normally disposed in spaced-apart relation and being movable towards each other for clamping an umbilical cord between the arms, identification means comprising a gender-identifying color associated with a portion of the clamp to facilitate identification of the gender of a baby while the clamp remains on the baby's cord, and a locking portion for securing the arms together when the clamp is closed.

In one embodiment, the gender-identifying color includes blue for a boy and pink for a girl.

In other embodiments, the entire clamp comprises one or more shades of the color, the color is visibly imbued within or painted upon the clamp, or both. In a preferred embodiment, a portion of the clamp is blue and the remainder is a neutral color for a boy and a portion of the clamp is pink and the remainder is a neutral color for a girl.

The invention also encompasses a method of identifying the gender of a newborn baby by applying the clamp with gender-identifying color and visually analyzing the identification means to determine the gender of the baby.

In yet another embodiment, the identification means further comprises an alphanumeric indicia, security apparatus, or a bar code to inhibit or prevent unauthorized removal of the baby from a pre-defined area. In a preferred embodiment, the invention encompasses a method of identifying a newborn baby by applying this clamp and analyzing the identification means to determine the mother of the newborn so as to minimize the chance of misidentification of the baby or the mother thereof. In another preferred embodiment, the invention relates to a method of inhibiting or preventing unauthorized removal of a newborn baby from a pre-defined area by applying this clamp and analyzing the identification means to determine at least the date and time of birth of the baby, and permitting only an authorized person to remove the baby from the pre-defined area.

Claims 26-28, which now depend from allowed claims 1-11, relate to an umbilical cord clamp that further includes a channel that extends substantially along the length of at least one arm and is open at the free end portion thereof to facilitate the escape of fluid therefrom when the clamp is closed. In one embodiment, the channel extends substantially along the length of each arm. In another embodiment, the channel has a width of about 1/4 to 1/2 of a width of each arm. In yet another embodiment, which is recited in claim 29, the depth of the channel of this clamp increases toward each open end.

VI. Grounds of Rejection to be Reviewed on Appeal

The rejections of:

(A) claims 17-25 under 35 U.S.C. § 103(a) over U.S. Patent No. 5,006,830 to Merritt ("Merritt") in view of U.S. Patent No. 6,132,447 to Dorsey ("Dorsey"); and

(B) dependent claim 29 under 35 U.S.C. § 102(b) over U.S. Patent No. 5,938,666 to Reynolds et al. ("Reynolds"),

are respectfully submitted to be improper and should be reversed on appeal.

VII. Argument

Applicant appreciates the courtesies extended by Examiner Pedro Philogene during an interview on February 2, 2005 with Applicant's attorney, Jeffrey A. Wolfson. The comments appearing herein relate only to claims 17-25 and claim 29 and these are substantially in accord with those presented and discussed during the interview.

A few minor amendments have been made to claim 17 to reduce the issues for appeal including to resolve potential antecedent basis issues with respect to a baby and the cord, and to more clearly recite that the clamp is adapted and configured to identify the baby's gender while clamped onto the baby, and to claim 27 to clarify the antecedent basis for the channel of claim 26. Claims 26-28 have been amended to depend from claim 1, and claim 26 has been further amended to remove duplicative features already recited in claim 1. No estoppel is intended to attach to these amendments, which are not believe to modify the claim scope either to enlarge or narrow the invention recited therein. In this regard, it is respectfully submitted that claim 29 remains separately patentable, as this feature is not disclosed or suggested by the prior art of record. As such, claim 29 has been simply written in independent form for consideration on appeal. No new issues have been raised and no new matter has been added by way of these amendments, such that their entry at this time is warranted. Moreover, the changes to claims 17, 26-27, and 30 are intended to reduce the issues for appeal or allowance.

Submitted herewith is a copy of a Declaration Under 37 C.F.R. § 1.132 of George H. Small (the "Small Declaration") in support of the patentability of the claims. In view of the prior allowance of all claims of this application on August 6, 2003 and payment of the issue fee on October 9, 2001, it was not previously believed necessary to submit additional evidence or information in the form of a Declaration to help demonstrate the patentability of the claims. Rather, it is only in view of the final Office Action mailed August 11, 2004 and the in-person interview with Examiner Philogene on February 2, 2004 that the necessity of a Declaration became apparent. Moreover, the secondary reference was issued on October 17, 2000, less than a

year before this application was filed, and with the passage of additional time, the long-felt, but unsolved needs in the art, which are addressed in the Small Declaration, have now become more apparent. Therefore, it is respectfully submitted that these reasons provide good and sufficient cause why the Small Declaration is necessary and was not previously submitted.

Claims 17-25 were rejected under 35 U.S.C. § 103(a) as being obvious over Merritt in view of Dorsey on pages 3-4 of the Office Action. The Office Action states Merritt provides all the features of claim 17 except the gender-identifying color associated with a portion of the clamp. The Office Action then relies on Dorsey in a "similar art" to allegedly evidence use of a device "to provide umbilical devices with gender-identifying color coding" for readily recognizable indicia associated with newborns, and that this would have been recognized as being readily adapted for umbilical cord severing.

Merritt discloses an umbilical cord clamp that contains particular types of *unique* identification marks including a serial code, bar code, color code, or letter combination, each of which has a different *distinctive* mark thereon (Col. 4, lines 10-24). Merritt fails to disclose the inclusion of a color, including shades thereof, to provide identification means comprising a gender-identifying color to facilitate identification of the gender of a baby, as presently recited. At best, it discloses a *color code* to prevent unauthorized removal of a newborn from a pre-defined area. Thus, Merritt requires a color code, which is presumably at least a pattern of multiple colors, *e.g.*, a multi-colored bar code, to provide identification for its stated purpose of preventing unauthorized removal of a baby from a security zone (*See, e.g.*, Small Declaration at ¶ 6).

On the contrary, Dorsey is directed to a completely different article--blue or pink labeled scissors used to cut an umbilical cord, rather than a clamp to hold the remaining portion of the cord. Dorsey's scissors do not remain with the newborn or in association with the umbilical cord, but instead are separately packaged and provided in a nice display for the parents. At best, Dorsey provides a novelty toy to new parents, or perhaps a souvenir of the baby's birth in the hospital (*See, e.g.*, Small Declaration at ¶ 7). Dorsey does not, however, teach to provide a gender-identifying means that is clamped onto the newborn's umbilical cord or otherwise associated with a portion of the clamp to facilitate identification of the gender of the baby (*See, e.g.*, . While Dorsey is simply a reminder to anyone seeing it that the possessor has a *child* is of a particular gender, claim 17 recites that the gender-identifying means facilitates identification of the gender of a baby while the clamp remains on the baby, i.e., the gender-identifying means remains with the baby until the umbilical cord stump and/or clamp fall off or are physically removed. This natural falling off of the cord with clamp on it typically takes 2 to 4 weeks for a typical baby, which is significantly and surprisingly longer than the momentary contact Dorsey

teaches while the cord is cut. Dorsey's colored scissors are never on the baby, as presently recited, as they are momentarily used to cut the umbilical cord (*See, e.g.*, Small Declaration at ¶ 7).

Aside from a hindsight rejection, it is not seen that the references themselves provide sufficient motivation that one of ordinary skill in the art would have combined them, much less arrived at the claimed article and methods. Merritt discloses an identification system to deter the unauthorized removal of a newborn from a defined area, while Dorsey provides blue or pink scissors to cut a baby's umbilical cord. Aside from both generally relating to the birthing experience, the references themselves contain absolutely no motivation whatsoever to suggest to one of ordinary skill in the art that they could have been combined in some way (*See, e.g.*, Small Declaration at ¶¶ 8 and 12).

It is settled law that bald assertion is not sufficient to maintain this rejection, as the Federal Circuit requires that a teaching or motivation to combine be present in the cited art of record. In the obviousness context, a motivation must have existed for one of ordinary skill in the art to combine the references--and this lack of such a motivation in the art of record demonstrates the patentability of the claims over the cited references, or at the very least demonstrates the lack of a *prima facie* case of obviousness by the Patent Office. *In re Lee*, 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (Fed. Cir., 2002) (finding that the Board of Patent Appeals and Interferences improperly relied upon common knowledge and common sense of person of ordinary skill in art to find invention of patent application obvious over combination of two prior art references, since factual question of motivation to select and combine references could not be resolved on subjective belief and unknown authority). Absent the motivation to combine a gender-identifying color on a pair of novelty scissors, with a cutting function, with a color code for security purposes on an umbilical cord clamp, Merritt and Dorsey failed to provide those of ordinary skill in the art with any motivation to select the gender-identifying color of Dorsey in hindsight and apply it to the uniquely coded article of Merritt (*See, e.g.*, Small Declaration at ¶¶ 8 and 12).

For example, the final Office Action states that Merritt teaches a clamp that remains on the baby, *i.e.*, on the cord stump of the baby, and Applicant readily acknowledges this. Dorsey and Merritt, however, still fail to provide a motivation to for one of ordinary skill in the art to provide a gender-identifying color from scissors onto a clamp to provide a gender-identifying function by remaining with the baby for a period of time (*See, e.g.*, Small Declaration at ¶¶ 7-8). Dorsey's separate scissors, with a cutting function, simply do not provide a motivation to keep the presently recited gender-identifying color with the baby, or even to use its colors to identify the gender of the baby, as Dorsey teaches to place the scissors in a frame or package

immediately after cutting the cord (*Id.*). As such, even the combination fails to teach the presently recited clamp with gender-identifying color (*Id.*).

In fact, Dorsey *teaches away* from Merritt, because Merritt discloses that every clamp should have a different distinctive identification mark thereon. Dorsey, however, teaches use of the pink and blue coatings on its scissors to identify gender (Col. 2, lines 13-27) of an entire class of people rather than a unique security identifier. Dorsey thus teaches a gender-identifying color on a pair of scissors that is not associated with a baby and that is not a sufficient universe of colors to create a security code, *e.g.*, a "color code," or to uniquely and distinctly identify every newborn in a given hospital or health care facility as required by the fundamental purpose of Merritt's teachings (*See, e.g.*, Small Declaration at ¶¶ 6-8). While Dorsey does teach other colors like green and yellow, which are used when the baby's gender is undetermined, this does not provide the missing motivation to combine the references.

Moreover, Dorsey teaches that the scissors are *separated from the baby* to be cleaned after severing the umbilical cord from the mother, further processed (labeled with birth data), framed or packaged, and presented to the child's parents (*See, e.g.*, FIG. 3 and Small Declaration at ¶ 8). On the contrary, it is essential for Merritt's clamp to *remain on the baby* to provide its inventive security function. Merritt's clamp, to function as intended, is processed before application to the baby for maximum security, while Dorsey's scissors are processed after cutting and do not remain with the baby. Indeed, Dorsey's scissors are not intended to function as a gender-identifying means, because they are *provided to the child's parents* rather than remaining on or even necessarily near the baby (*See, e.g.*, Small Declaration at ¶ 7). This also teaches away from placing a clamp on a baby, as taught by Merritt. In view of these significantly different purposes and functions, one of ordinary skill in the art would not have been motivated to combine selected features from Dorsey and Merritt in the absence of guidance from the present specification regarding the presently recited surprising and unexpected invention (*See, e.g.*, Small Declaration at ¶¶ 8 and 12).

Moreover, there has been a long-felt, but unsolved need in the art for the claimed articles and methods (*See, e.g.*, Small Declaration at ¶¶ 9-12). This is an important secondary consideration that requires consideration in connection with the present obviousness rejection. Umbilical cord clamps have been used to assist in delivery of newborns for decades, at least in various developed countries. The basic model clamp has been in use for much of that time without significant changes. Indeed, allowed claims 1-11 are another such improvement that the Applicant, Dr. Small, believes is highly desired and resolves yet another long-felt but unsolved problem in the art. The problem of clamps flying away from the application area due to slippery,

blood covered gloves during clamp application is well known in the art, yet no solution has been achieved until the presently recited invention of claims 1-11.

Yet another problem in the art is the failure of a reliable method for visitors to the newborn, as well as the parents and hospital staff, to rapidly, accurately, and repeatedly, identify the gender of babies without removing their diaper, *e.g.*, so the proper pronoun can be used (*See, e.g.*, Small Declaration at ¶¶ 9 and 12). This problem is well known in post-natal wards, and to date one of the best solutions involves use of blue or pink baby hats or other clothing. Unfortunately, these tend to fall off of babies, and tend to be applied improperly sometimes when exhausted health care workers re-apply the hat or other colored clothing to a baby after various treatments. Thus, not only do such hats or clothing not always remain with the child, but the wrong color may be applied to the child at various times causing temporary confusion (*See, e.g.*, Small Declaration at ¶ 9).

The long-felt need has not yet been satisfied to the knowledge of the Applicant, Dr. Small, who began delivering children more than 25 years ago (*See, e.g.*, Small Declaration at ¶ 10 and 12). Indeed, as far as Applicant knows, the invention of Dorsey, or the alleged combination of Merritt and Dorsey, has not been adopted by anyone else in the field of art (*Id*). Thus, the long-felt need still requires a solution, which has been elegantly and cleverly achieved by the surprising and unexpected invention presently recited in claims 17-25 (*See, e.g.*, Small Declaration at ¶¶ 10-11). The surprising and unexpected advantages of the claimed invention relative to conventional gender identification (*See, e.g.*, Specification at page 10, lines 17-28) are clear in view of the present specification. The present invention elegantly solves this problem by applying a gender-identifying clamp to a nude newborn at birth--when the chance for gender misidentification is significantly lower than later times when clothes are worn (*See, e.g.*, Small Declaration at ¶ 11-12). The clamp of the invention does not typically fall off, either, and remains with the diapered-newborn baby until the cord falls off, which is generally after the baby departs from the hospital or other pre-defined area (*See, e.g.*, Small Declaration at ¶ 11). The simple fact is that millions of babies are delivered annually, and to the Applicant's knowledge no one has ever achieved such a simple, elegant solution to the problem of gender misidentification of newborn babies (*See, e.g.*, Small Declaration at ¶ 10-12). In fact, it should be clear common sense (in hindsight) that there is a long-felt need in the obstetric art for the improved gender-identifying clamp provided by the claimed invention. For these and other reasons, the rejection under 35 U.S.C. § 103(a) has been overcome and should be reconsidered and withdrawn, particularly since no *prima facie* case of obviousness has been stated on the record even in view of the combination of cited references.

Claim 26-30 were rejected under 35 U.S.C. § 102(b) over Reynolds on page 2 of the Office Action. The Office Action states that Reynolds identically discloses each and every feature recited by claims 26-30. Applicants have amended claim 26-28 to directly or ultimately depend from claim 1, and claim 30 has been canceled.

Claim 29 recites that the depth of the channel increases toward each open end. Reynolds fails to disclose or even suggest this feature. Rather, Reynolds does not even acknowledge that it would be desirable to increase the channel in one direction or the other. Reynolds not only fails to disclose that the channel depth increases toward the open ends of the clamp arms, but it *teaches away* from the claimed invention by disclosing that the webs (21,22) are *parallel to and preferably co-planar* to the root plane of opposite interior serrated surfaces, so blood is forced out of the vessels and artery of the cord in *opposite directions* (Col. 4, lines 38-42). This teaches that blood is removed out either end of the clamp arms. On the contrary, claim 29 recites a structure where the net blood flow will occur only in one direction--the direction of the open end where the channel depth is increased. Thus, Reynolds fails to teach each and every recited feature of claim 29, such that the rejection of claim 29 under 35 U.S.C. § 102(b) should be reconsidered and withdrawn.

Accordingly, Applicant submits that all claims are again in condition for allowance in view of the MPEP and the relevant law regarding obviousness, particularly the lack of motivation to combine references and the long-felt but unsolved need in the art. Should the Examiner not agree with this position, a telephone or personal interview is requested to resolve any remaining issues and expedite allowance of this application, *e.g.*, by Examiner's Amendment.

Respectfully submitted,

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Date

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